

teaching or suggestion for combining prior art references in creating an obviousness rejection “stands as a critical safeguard against hindsight analysis . . .” *In re Rouffet*, 47 U.S.P.Q. 2d at 1458.

In this regard, Applicants respectfully submit that the Patent Office has failed to establish that one skilled in the art, viewing the cited references, would be motivated to combine their teachings to arrive at the claimed invention. Although the Patent Office asserts that the primary reference, namely *Lichtenstein*, discloses an extracorporeal blood circulation and treatment system, including modules for drug infusion that can be controlled by a computer, *Lichtenstein* does not disclose a touch screen as a user interface for the computer as even admitted by the Patent Office. Further, Applicants believe that *Lichtenstein* provides no teaching or suggestion which would lead a skilled artisan to contemplate incorporating a touch screen with the computerized blood-treatment system as disclosed in *Lichtenstein*.

Indeed, *Lichtenstein* fails to disclose any teaching or suggestion as to, for example, why a touch screen would be beneficial or desirable in a hemodialysis machine, how a touch screen could incorporate the complex controls and displays necessary in a hemodialysis machine, what operating parameters could be controlled or displayed using a touch screen, or how data concerning any operating parameters of a hemodialysis machine could be displayed or changed using a touch screen. Based on the deficiencies of *Lichtenstein*, Applicants believe that one skilled in the art viewing *Lichtenstein* would clearly not be motivated to modify *Lichtenstein* to include a touch screen user interface as required by the claimed invention.

Further, Applicants respectfully submit that nowhere do the other cited references provide support for combining their alleged touch screen teachings with the teachings of *Lichtenstein* to arrive at the claimed invention. Both *Kerns* and *Rubalcaba* clearly relate to portable modular infusion-pump systems for delivering medicaments to a patient and not an

extracorporeal blood treatment system, a hemodialysis system, operating a hemodialysis system, or what parameters are pertinent to operating a hemodialysis system. *Rubalcaba*, column 3, lines 21-27; *Kerns*, column 2, lines 45-59 and column 12, lines 3-4.

A modular drug-infusion system according to either *Rubalcaba* or *Kerns* merely displays a limited amount of patient information obtained from sensors, such as an oxymeter or blood pressure monitor, (*Kerns*, column 2, lines 49-59), and can calculate, display, and store a separate set of parameters for each infusion module (*Rubalcaba*, column 8, lines 35-41). However, the addition of a touch screen to a hemodialysis machine is not the same as simply adding a different style of gauge or changing an arrangement of controls. Indeed, providing a hemodialysis machine with a touch screen requires extensive innovation in hardware and software. This is due, in part, to the fact that a hemodialysis machine is a complex apparatus with a large number of components that must be controlled very accurately and precisely to ensure patient safety and comfort.

Neither *Kerns* nor *Rubalcaba* provides any hint to a skilled artisan regarding how to develop or integrate the complex software and hardware required to replace some or all the electromechanical controls and displays of a conventional hemodialysis machine with a functional touch screen. In contrast, the respective apparatus described in *Kerns* and *Rubalcaba* are directed primarily to modular drug infusion pump systems based on a "central management unit" connected to a plurality of (e.g., four) identical pumping modules. See, e.g., *Kerns*, FIG. 1 and column 2, lines 49-59; *Rubalcaba*, FIG. 1 and column 3, lines 8-27. The central management unit calculates drug-delivery rates based on data supplied by the user. See, e.g., *Kerns*, column 10, lines 18-68; *Rubalcaba*, column 4, line 22 to column 5, line 68. However, neither reference provides any teaching or suggestion of how to provide comprehensive

monitoring and controlling of the multitude of complex parameters inherent in operating a hemodialysis machine using a touch screen or any other user interface.

Applicants also believe that the Patent Office has clearly mischaracterized the teachings of both *Kerns* and *Rubalcaba*. For example, the Patent Office specifically cited to column 1, lines 41-59 of *Kerns* to support its rejection. The cited text of *Kerns* summarizes the use a central management unit, not a touch screen, to control a number of mechanically identical drug-infusion modules connected to the central management unit. The central management unit is used to control the internal setup of the modules and to receive and display information from the modules (which are normally stacked atop one another during operation). The central management unit is also used for the following purpose:

In order to prevent confusion of data due to the detachment and reattachment of modules in possibly different orders, the central management unit of this invention automatically keeps track of the identity of various modules regardless of their position in the module stack attached to the central management unit.

Kerns, column 1, lines 54-59.

However, this cited text in *Kerns* does not mention a touch screen or suggest why combining a touch screen with a hemodialysis machine would be desirable. Any "confusion of data" identified in *Kerns* arises solely from the switching and rearrangement of different drug-infusion modules in the stack. Indeed, the explicitly stated object of the *Kerns* apparatus addresses this problem:

It is therefore the object of the invention to provide a portable, centrally-managed integral set of selectably removable modular units for pumping and monitoring purposes, each unit being adapted to be programmed and monitored through the central management unit but being capable of functioning independently when detached therefrom.

Kerns, column 2, lines 7-13.

Therefore, Applicants believe that the clear objective for *Kerns* to prevent confusion of data in the context of multiple, identical, stackable pump modules does not provide a level of teaching or suggestion which would necessarily motivate one skilled in the art to combine a touch screen with a hemodialysis machine.

With respect to *Rubalcaba*, this reference sought to correct another problem unique to modular drug-infusion systems by:

providing a system with a touch screen calculator arrangement that automatically calculates, displays, and stores a separate set of parameter values for each one of the infusion pump modules.

Rubalcaba, column 2, lines 8-11.

This feature provided a specialized calculator capable of retaining data when the drug-infusion modules were switched on the stack. *Rubalcaba*, column 1, line 56 to column 2, line 4. According to *Rubalcaba*, the specialized calculator, in the context of multiple stacked infusion-pump modules, and not hemodialysis systems substantially lowered the chance for user confusion and error. *Rubalcaba*, column 8, lines 40-41. Thus, Applicants believe that *Rubalcaba* provides no disclosure or suggestion that a hemodialysis machine, as known on the priority date of the instant application, had any problem with "user confusion and error" in this same described context.

Based on the fact that the Patent Office has clearly not established a motivation to combine the references, Applicants believe that the Patent Office has improperly applied hindsight reasoning to reject the claimed invention in view of the cited references. Of course, hindsight reasoning is an improper basis for an obviousness rejection. *In re Rouffet*, 149 F.3d at 1357-1358, 47 U.S.P.Q.2d at 1457-1458.

Of the cited references, *Lichtenstein* was clearly deficient. Although *Lichtenstein* provides a general teaching regarding extracorporeal blood systems, it clearly fails to teach or

suggest combining a touch screen with a hemodialysis apparatus as required by the claimed invention. Further, the clear focus of the teachings of *Kerns* and *Rubalcaba* relate to infusion pump systems and not hemodialysis systems. Thus, Applicants believe that the teachings relating to infusion pumps as disclosed in *Rubalcaba* and *Kerns* would not motivate one skilled in the art to combine a touch screen with a hemodialysis apparatus as required by the claimed invention.

Therefore, Applicants believe that the Patent Office has failed to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully submit that the obviousness rejection of Claims 30-41 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in a condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204